

REMARKS

The Office Action mailed January 29, 2009, has been received and carefully noted. The above amendments and the following remarks are being submitted as a full and complete response thereto.

Prior to entry of this amendment, Claims 1-13 were pending in the application and Claims 6-8 were withdrawn from consideration.

New Claims 14 and 15 are added. Claim 14 contains limitation of original Claim 1 and some technical features taken from the description, while Claim 15 contains limitations of Claims 1 and 2. Claim 2 is cancelled.

Claims 1-3, 5, and 9-12 are amended in order to meet formal requirements.

In particular, it is to be noted the amended claims and new added claims do not introduce new matter, since they contain only limitations that were already disclosed in the original specification and claims.

Election/Restriction

Claim 13 was not considered by the Examiner and held to be withdrawn by a constructive election by prosecution as a subcombination of the combination invention already examined. This holding of restriction by the Examiner is traversed. Claim 13 is a further detailed claim than Claim 9 which was examined. The body of the claim contains the limitations of Claim 1. It is not a separately claimed device.

Under MPEP 806.05(c), the Examiner is required to specifically set forth two-way distinctness and reasons for insisting that restriction is necessary, i.e., there would be a serious search burden if restriction was not required as evidence by separate

classification, status, or field of search. See MPEP 808.02. The subject matter claimed should have been searched at the time of initial examination since it would have been reasonably foreseeable that the applicant might amend the claims to include the details of the transducer means. Consequently, the restriction is improper and untimely. Examination going forward of the subject matter of claim 13 is requested.

Claim Rejections - 35 U.S.C. §103

Claims 1-5 and 9-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over admitted prior art (Background of the invention) in view of Trebbi (U.S. Patent No. 6,327,835, hereinafter "Trebbi"). Applicant respectfully traverses this rejection.

In order to overcome the Examiner's objections, Applicant has amended Claim 1 by specifying that detecting and checking means comprises volume transducer element.

As already stated, the Background of the invention discloses a capsule filling machine in which the only quality control on the capsules is performed in a statistic way by high precision scales at the end of the production process.

As stated by the Examiner, Trebbi discloses a capsule filling machine having "detecting means to check out the quantity of the material filled into the capsules body."

The Examiner is holding that the metering device of Trebbi is the equivalent of the claimed structure. In order to be equivalent, the structure ought to (1) perform the exact function claimed and (2) do so in substantially the same way to achieve substantially the same result as the structure disclosed in the specification.

Trebbi does not perform the exact function in that Trebbi does not measure a volume of the quantities of the pharmaceutical material before they are inserted into the

capsule bodies. The pressing thrusters transducers measure resistance of the already filled material which is taken to be a parameter of density, and thereby enabling calculation of mass.

Applicant wants to underline that Trebbi does not show any volume transducer element, but rather a volumetric metering device. Therefore the device disclosed by Trebbi does not measure or control an already dosed quantity of pharmaceutical product, but itself sets the correct amount and thereafter checks.

Therefore the metering device of Trebbi functions in a different way and it is not equivalent to the claimed device.

In the light of the above, Claim 1 is also inventive.

Claims 3-5 and 9-12 are patentable as well since they depend on a non-obvious Claim 1.

With regard to Claim 14, Applicant believes that this claim is not obvious in view of the available prior art.

Claim 14 contains the same limitations of previously amended Claim 1 and better specifying how the transducer element is made.

Evidently, Trebbi does not disclose any transducer element for measuring a volume of said quantities before they are inserted into the capsule bodies. Moreover, Trebbi does not disclose that the transducer element comprises a sliding detector element designed to vertically slide and enter in a respective dosing chamber associated with the carousel of the filling machine to measure a height reached by the quantity of pharmaceutical material in the dosing chamber.

Indeed, Trebbi discloses volumetric metering devices (numbered as 8 and 9) comprising the hollow punch (18) inside which there is a movable arranged a small piston (19) to isolate volumetrically predefined metered amounts of the product. The volume of the predefined metered amounts of the product is defined by the fixed distance of the piston (19) from the lower edge of the hollow punch (18).

In the Trebbi's machine, the force transducer measures indirectly the density of the material by measuring the force necessary to penetrate in the material for the same stroke of the thrusters. In other words, the machine described in Trebbi can estimate the quantity (the mass) of the pharmaceutical material filled into each capsule body by means of an indirect measurement of the density and of a known value of the volume.

In view of the above, the combination of Trebbi with the admitted prior art does not lead to the claimed solution.

Therefore, present Claim 14 is not obvious over admitted prior art (Background of the invention) in view of Trebbi.

Claim 15 also discloses that checking means also comprises a dose checking disc coupled with the carousel.

The disc presents at least one series of dosing chambers of predetermined size, inside each of which the quantity of pharmaceutical material is temporarily placed. The volume transducer element is designed to operate in the chambers to measure the volume of the quantities of pharmaceutical material before they are inserted into the respective capsule bodies.

As already stated, the Background of the invention discloses a capsule filling machine in which the only quality control on the capsules is performed in a statistic way by high precision scales at the end of the production process.

As stated by the Examiner, Trebbi discloses a capsule filling machine having “detecting means to check out the quantity of the material filled into the capsules body. “

Trebbi does not disclose any transducer means for measuring a volume of said quantities dosed directly into a dosing chamber, before they are inserted into the capsule bodies.

Moreover, Trebbi does not disclose any dose checking disc, coupled with the carousel, and presenting at least one series of dosing chambers of predetermined size, inside each of which the quantity of pharmaceutical material is temporarily placed.

Trebbi discloses a device capable of collecting and storing a dosed amount of product inside itself, and transferring it inside each capsule.

Therefore Trebbi does not disclose a volume transducer element designed to operate in the dosing chambers to measure the volume of an already dosed quantity of pharmaceutical material before they are inserted into the respective capsule bodies.

The volume transducer element is designed to operate in the chambers to measure the volume of the quantities of pharmaceutical material before they are inserted into the respective capsule bodies.

Trebbi discloses a volumetric metering device, therefore a device which doses the quantity of product. By contrast the present invention discloses not a volume transducer element, therefore an element which values if the already dosed amount is correct.

Therefore, the device disclosed by Trebbi is not equivalent to the claimed transducer element.

For at least the above reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of Claims 1-5 and 9-12 under 35 U.S.C. §103(a) over the admitted prior art in view of Trebbi.

Conclusion

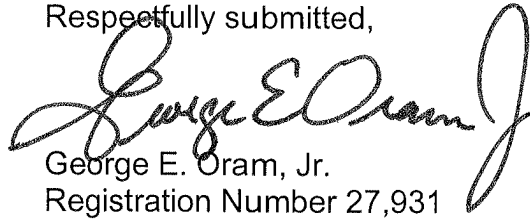
All matters having been addressed above and in view of the pending claims and remarks, Applicant respectfully requests the entry of this Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims.

Applicant's counsel remains ready to assist the Examiner in any way to facilitate and expedite the prosecution of this application.

Applicant respectfully submits that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event that this paper is not being timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account Number 01-2300, referencing Docket Number 023349-00315.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "George E. Oram, Jr.", written over the typed name and registration number.

George E. Oram, Jr.
Registration Number 27,931

Customer Number 004372
ARENT FOX LLP
1050 Connecticut Avenue, NW
Suite 400
Washington, DC 20036-5339
Telephone: 202-857-6000
Fax: 202-638-4810

GEO:vmh